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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/830,986

Applicant(s)

BERNKOP-SCHNURCH,  
ANDREAS

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on December 16, 2005, April 20, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,28-33 and 35-109 is/are pending in the application.
- 4a) Of the above claim(s) 39-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,28-33 and 35-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April , 20, 2005 has been entered.

Claims 1, 28-33, 35-109 are pending. Applicant's election with traverse of Group I, claims 1, 28-33, 35-38 and the species thiolated copolymers of acrylic acid and divinyl glycol as recited in claim 30 for examination, in the reply filed on December 16, 2005 is acknowledged. The traversal is on the ground(s) that the claims have been search before and now they do not pose a serious burden of search. This is not found persuasive because as explained in the Requirement, there exist a lack of unity independent of the burden of search. Thus, the claims are patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-109 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 15, 2005.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A search was conducted towards the elected species and the claims were found to be free of art to the extent that they read on the elected species. Accordingly, a claim directed to a mucoadhesive thiolated copolymer of acrylic acid and divinyl glycol wherein the copolymer contains at least one non-terminal thiol group and exhibits a total work of adhesion of more than 120  $\mu$ J to intestinal mucosa at a pH of 7 would be free of art.

However, the search was then extended to include other polymers that contain not more than 10 different monomers and at least one non-terminal thiol group that can inherently provide the claimed total work of adhesion.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claim recites wherein the thiol groups are cysteine groups which renders the claim ambiguous. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "thiol" in claim

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31 is used by the claim to mean "cysteine group", while the accepted meaning is "-SH."

The term is indefinite because the specification does not clearly redefine the term.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 33, 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Omura et al US Patent 5,064,495.

Omura discloses methods of improving adhesion properties of a polymer to a metallic compound wherein the polymeric compositions contains at least one mercapto or thiol group that is not a non-terminal thiol group. (see abstract, col 28, lines 20-33; col 2, lines 25-46; col 3-4, the third monomer from the bottom of the page; col 5-6, the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 6<sup>th</sup>, 7<sup>th</sup>, 9<sup>th</sup>, 10<sup>th</sup>, 11<sup>th</sup>, monomeric units, also see col 9-12). Omura

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describes that the polymeric entity is prepared by condensation of methacrylic acid anhydride various type of compounds that contain a non-terminal thiol (mercapto unit) (see col 15-18, especially col 15, lines 1-40; col 16, lines 39-67; col 18, lines 21-54 and col 19-21). Since Omura's polymeric compositions meet all elemental limitations of the instant claims, they can also exhibit their functional total work of adhesion limitation.

Claims 1, 30-33, 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Constancis et al US Patent 5,646,239.

Constancis teaches oligomeric moieties that contain a side chain thiol group at position R1 or R2 (see col 4, line 55-col 6, line 54). Constancis teaches that the copolymer are a function of the combination of succinic acid and cysteine (see col 5, lines 50-65; col 13-cl 16). Constancis further states that his oligomers can be synthetically attached to such biological macromolecules such as mucopolysaccharides including hyaluronic acid, chitosan and cellulose to render such polymers thiolated (see col 6, lines 8-15). Since Constancis polymeric compositions meet all elemental limitations of the instant claims, they can also exhibit their functional total work of adhesion limitation.

Claims 1, 31-33, 35-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Marchant US Patent 6,514,535.

Merchant describes bioadhesive compositions comprising mucoadhesive polymeric units containing at least one non-terminal thiol group on the side chains (see col 9, line 45-col 10, line 25; col 18, line 50-col 19, line 26). The monomeric unit can contain cystine (see col 10, lines 1-10; col 13, line 60-col 14, line 61). Merchant

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specifically states that his compositions contain an active agent attached to a polymer with thiol side group which can be used to delivery the active thiol containing therapeutic formulations. (see col 10, lines 50-65). Since Merchant's polymeric compositions meet all elemental limitations of the instant claims, they can also exhibit their functional total work of adhesion limitation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constancis or Merchant.

The teachings of Constancis and Merchant are described above. Their individual teachings fail to specifically state the concentration of covalently bound thiol groups per gram of polymer as recited in instant claims 28-29.


However, absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the degree and amount of thiol group to the core polymeric backbone of Constancis or Merchant by routine experimentation, because the ordinary skill in the art would have been motivated to maximize the adhesion properties of such polymeric units.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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